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08/22/2003

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EXAMINER

WELLS, LAUREN Q

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 08/22/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application N .

09/762,431

Applicant(s)

SHALABY ET AL.

Examiner

Lauren Q Wells

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 2-28 is/are pending in the application.
- 4a) Of the above claim(s) 2-10, 13-18 and 20-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11, 12 and 19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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### **DETAILED ACTION**

Claims 2-28 are pending. Claims 2-10, 13-18 and 20-28 are withdrawn from consideration, as they are directed toward non-elected subject matter. The Amendment filed 5/22/03, Paper No. 14, cancelled claim 1, and amended claims 11 and 19.

Two information disclosure statements were filed 5/22/03. One of the IDS's filed is a copy of the IDS filed 1/24/02. References that were previously considered by the 1/24/02 IDS were marked out as "already considered" on the IDS filed 5/22/03. The other IDS filed 5/22/03 listed references that were identical to a number of references on the IDS filed 5/22/03, which is a duplicate of the IDS filed 1/24/02. Thus, the duplicate references were marked out on the IDS filed 5/22/03, which is a duplicate of the IDS filed 1/24/02, as already considered. However, the IDS filed 5/22/03, which is a duplicate of the IDS filed 1/24/02, failed to provide a reference by Moa et al. (see sheet 2 of 3). Thus, this reference has not been considered.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11, 12 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(i) Claims 11, 12, and 19 are vague and indefinite, as they depend from a claim that has been cancelled. The metes and bounds of these claims are unascertainable.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 11 and 19 are rejected under 35 U.S.C. 102(a) or (e) as being anticipated by Kaizawa et al. (5,686,540).

Kaizawa exemplifies a lactic acid-based polyester comprising L-lactide/D-lactide (98/2), terephthalic acid, ethylene glycol, and tartaric acid. See Col. 19, lines 40-64.

It is respectfully pointed out that the limitations in the preamble of claim 11 of an absorbable polyester and of claim 19 directed to the use of the polyester of claim 11 do not render the claims patentable. The absorbability of the polyester is an inherent property and is not given patentable weight. See US 5,635,216, col. 3, lines 55-61.

Terms merely setting forth an intended use for, or a property inherent in, an otherwise old composition do not differentiate the claimed composition from those of the prior art. In re Pearson, 181 USPQ 641. Difference in use cannot render a claimed composition novel. In re Tuominen, 213 USPQ 89. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties Application discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product does not inherently possess the same properties as instantly claimed product.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kakizawa as applied to claims 11 and 19 above.

The instant invention is directed toward a polyester, wherein the polyester chain comprises one or more monomers selected from lactic acid, malic acid, citric acid, tartaric acid, caproic acid, alkylene oxalate, cycloalkylene oxalate, alkylene succinate, hydroxybutyrate, glycolide, glycolic acid, lactide, trimethylene carbonate, dioxanone, 1,4-dioxepane-2-one, 1,4-dioxepane-2-one, and any optically active isomers, racemates, or copolymers thereof.

Kakizawa is applied as discussed above. In Col. 6, lines 36-53, the reference teaches ethylene glycol, diethylene glycol, triethylene glycol, and polyethylene glycol as interchangeable

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diol components. The polyethylene glycol is taught as providing the polyester with excellent flexibility. The reference lacks an exemplification of polyethylene glycol as the diol.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute polyethylene glycol for ethylene glycol in the example described in the 102 rejection above over Kakiawa because polyethylene glycol and ethylene glycol are taught as interchangeable diols for use in the polyester and because of the expectation of achieving a polyester with excellent flexibility.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on M-F (7-5:30), with alternate Mondays off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (703)305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw  
July 2, 2003

  
RUSSELL TRAVERS  
PRIMARY EXAMINER